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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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INHALE THERAPEUTIC SYSTEMS, INC  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/888311

Applicant(s)

WGERL

Examiner

WCBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- ☒ Responsive to communication(s) filed on 3/14/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-29 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-29 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1617

Contrary to applicant's statement on page 5 line 1 paper #3, filed 3.14.02, claims 1,2 and 13 have not been<sup>n</sup> cancelled.  
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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards.

Edwards et al. discloses delivery of phospholipid matrix containing particles with a mass mean diameter between 5 and 30 microns and a tap (bulk) density of 0.4g/cm<sup>3</sup> which together yield an aerodynamic diameter of the particles of between 1 and 5 microns for use in a method of administration employing a passive dry powder inhaler (see abstract, lines 3-9, p. 6, lines 2-13, p. 8, lines 11-21, p.9, lines 12-13, p. 11, lines 23-27, p. 33, lines 23-29). Any agent can be incorporated (page 20 line 1 – page 21 line 14). <sup>ver</sup>One 35% of particles are considered respirable (page 34 lines 12-14). As to applicants' claimed properties, the disclosed inhale<sup>l</sup>r of commerce in combination with the disclosed particles, inherently provides the same delivery characteristics as claimed with like~~the~~ commercially available devices disclosed by applicants.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al in view of Van Oort et al.

Edwards is discussed above.

Van Oort et al. Discloses a method of administering a Hollow dry powder drug composition which comprises an anti-inflammatory drug as budesonide or an anti-infective drug, comprising the steps of 1) providing a dry powder drug composition having particle size of from about 1 to 5 microns, and 2) inhaling (see p. abstract, p.10, lines 9-12, p. 17, Table B). Improved desegregation is specified (page 6, lines 21-22).

It would have been obvious at the time the invention was made to use a hollow particulate in the method of Edwards et al to achieve the beneficial effect of improved deaggregation in view of Van Oort et al.

OK Claims 28-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a phospholipid, does not reasonably provide enablement for any particle. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On page 3 line 27 phospholipid particles are specified. No other is disclosed.

Claims 1, 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 "substantially" is vague; what % ? Applicants argue but do not claim the parameters disclosed on page 5 fourth paragraph, in paper #3, filed 3/14/02.

The examiner requests the references recited on page 3 lines 13-15, page 11 lines 29-30, and page 12 line 2 in the specification.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-0570. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
June 3, 2002

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500